Application No.: 09/445328

Docket No.: JJJ-P01-514

## In the Claims

Please cancel claims 1, 3-4, 7 and 39-52 without prejudice. Please also amend claims 2, 5-6, and 8-38 as follows:

- 1. (Canceled)
- 2. (Currently Amended) A method of [treatment to] delaying the need for, or reducing[e] the frequency of, dialysis treatments of a mammal afflicted with acute renal failure, the method comprising administering to said mammal a therapeutically effective amount of an OP/BMP renal therapeutic agent comprising a polypeptide comprising a sequence at least 70% homologous to the C terminal seven-cysteine domain of human OP-1, the sequence of the C terminal seven-cysteine domain of human OP-1 being set forth at residues 330-431 of human OP-1.
- 3. (Canceled)
- 4. (Canceled)
- 5. (Currently Amended) [A] The method [as in any one of claims 1-4] of claim 2, wherein said renal therapeutic agent comprises a polypeptide consisting of at least a C-terminal cysteine domain of a protein selected from the group consisting of a pro form, a mature form, and a soluble form of a polypeptide selected from the group consisting of OP-1, OP-2, OP-3, BMP2, BMP3, BMP4, BMPS, BMP6, and BMP9.
- 6. (Currently Amended) [A] <u>The</u> method as in claim 5 wherein said renal therapeutic agent comprises a polypeptide consisting of at least a C-terminal cysteine domain of a protein selected from the group consisting of a pro form, a mature form, and a soluble form of human OP-1.
- 7. (Canceled)

8. (Currently Amended) [A] <u>The</u> method [as in claim 7] <u>of claim 2</u> wherein said polypeptide has at least 75% homology with an amino acid sequence of a seven-cysteine domain of human OP-1.

- 9. (Currently Amended) [A] <u>The</u> method [as in claim 7] <u>of claim 2</u> wherein said polypeptide has at least 80% homology with an amino acid sequence of a seven-cysteine domain of human OP-1.
- 10. (Currently Amended) [A] <u>The</u> method [as in claim 7] <u>of claim 2</u> wherein said polypeptide has at least 60% identity with an amino acid sequence of a seven-cysteine domain of human OP-1.
- 11. (Currently Amended) [A] <u>The</u> method [as in claim 7] <u>of claim 2</u> wherein said polypeptide has at least 65% identity with an amino acid sequence of a seven-cysteine domain of human OP-1.
- 12. (Currently Amended) [A] <u>The</u> method [as in claim 7] <u>of claim 2</u> wherein said polypeptide has at least 70% identity with an amino acid sequence of a seven-cysteine domain of human OP-1.
- 13. (Currently Amended) A method [as in] of any one of claims [5-12] 5-6 and 8-12 wherein said renal therapeutic agent
  - (a) induces chondrogenesis in an ectopic bone assay;
  - (b) prevents, inhibits, delays or alleviates loss of renal function resulting from acute renal failure in an animal model of acute renal failure; or
  - (c) causes a clinically significant improvement in a standard marker of renal function when administered to a mammal in, or at risk of, acute renal failure.
- 14. (Currently Amended) [A] <u>The</u> method [as in any one of claims 1-4] <u>of claim 2</u> wherein said renal therapeutic agent is selected from the group consisting of human osteogenic proteins and human bone morphogenic proteins.
- 15. (Currently Amended) [A] <u>The</u> method [as in any one of claims 1-2] <u>of claim 2</u> wherein serial determination of BUN in said mammal indicates a rate of increase in BUN of at least 2 to 4 mmol/L/day (5 to 10 mg/dL/day).



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16. (Currently Amended) [A] <u>The</u> method [as in any one of claims 1-2] <u>of claim 2</u> wherein serial determination of BUN in said mammal indicates a rate of increase in BUN of at least 4 to 8 mmol/L/day (10 to 20 mg/dL/day).

- 17. (Currently Amended) [A] <u>The</u> method [as in any one of claims 1-2] <u>of claim 2</u> wherein serial determination of serum creatinine in said mammal indicates a rate of increase in serum creatinine of at least 20 to 40 μmol/L/day (0.25 to 0.5 mg/dL/day).
- 18. (Currently Amended) [A] <u>The</u> method [as in any one of claims 1-2] <u>of claim 2</u> wherein serial determination of serum creatinine in said mammal indicates a rate of increase in serum creatinine of at least 40 to 80 μmol/L/day (0.5 to 1.0 mg/dL/day).
- 19. (Currently Amended) [A] <u>The</u> method [as in any one of claims 1-2] <u>of claim 2</u> wherein said mammal is afflicted with a condition selected from the group consisting of pre-renal causes of acute renal failure, post-renal causes of acute renal failure.
- 20. (Currently Amended) [A] <u>The</u> method [as in] <u>of</u> claim 19 wherein said mammal is afflicted with a pre-renal cause of acute renal failure selected from the group consisting of decreased cardiac output, hypovolemia, volume redistribution, and altered vascular resistance.
- 21. (Currently Amended) [A] <u>The</u> method [as in] <u>of</u> claim 19 wherein said mammal is afflicted with a post-renal cause of acute renal failure selected from the group consisting of ureteral, pelvic and bladder obstructions.
- 22. (Currently Amended) [A] The method [as in] of claim 19 wherein said mammal is afflicted with an intrinsic renal cause of acute renal failure selected from the group consisting of abnormalities of the vasculature, abnormalities of the glomeruli, acute interstitial nephritis, intratubular obstruction, and acute tubular necrosis.

23. (Currently Amended) [A] <u>The</u> method [as in any one of claims 1-2] <u>of claim 2</u> wherein said mammal is a kidney transplant recipient.

- 24. (Currently Amended) [A] <u>The</u> method [as in any one of claims 1-2] <u>of claim 2</u> wherein said mammal possesses only one kidney.
- 25. (Currently Amended) [A] <u>The</u> method [as in any one of claims 1-4] <u>of claim 2</u> wherein said administration is oral.
- 26. (Currently Amended) [A] <u>The</u> method [as in any one of claims 1-4] <u>of claim 2</u> wherein said administration is parenteral.
- 27. (Currently Amended) [A] <u>The</u> method [as in any one of claims 1-4] <u>of claim 2</u> wherein said administration is intravenous.
- 28. (Currently Amended) [A] <u>The</u> method [as in any one of claims 1-4] <u>of claim 2</u> wherein said administration is intraperitoneal.
- 29. (Currently Amended) [A] <u>The</u> method [as in any one of claims 1-4] <u>of claim 2</u> wherein said administration is into the renal capsule.
- 30. (Currently Amended) [A] <u>The</u> method [as in] <u>of</u> claim 26 wherein a stent has been implanted into said mammal for said administration.
- 31. (Currently Amended) [A] <u>The</u> method [as in] <u>of</u> claim 30 wherein said stent is an intravenous stent.
- 32. (Currently Amended) [A] <u>The</u> method [as in] <u>of</u> claim 30 wherein said stent is an intraperitoneal stent.

33. (Currently Amended) [A] <u>The</u> method [as in] <u>of</u> claim 30 wherein said stent is a renal intracapsular stent.

- 34. (Currently Amended) [A] <u>The</u> method [as in] <u>of</u> claim 26 wherein said administration is by an implanted device.
- 35. (Currently Amended) [A] <u>The</u> method [as in any one of claims 1-4] <u>of claim 2</u> wherein said administration is daily for a period of at least about one week.
- 36. (Currently Amended) [A] <u>The</u> method [as in any one of claims 1-4] <u>of claim 2</u> wherein said administration is at least once a week for a period of at least about one month.
- 37. (Currently Amended) [A] <u>The</u> method [as in any one of claims 1-4] <u>of claim 2</u> wherein said renal therapeutic agent is administered at a dosage of about 0.01-1000 μg/kg body weight of said mammal.
- 38. (Currently Amended) [A] <u>The</u> method [as in] <u>of</u> claim 37 wherein said renal therapeutic agent is administered at a dosage of about 0.1-100 μg/kg body weight of said mammal.

39-52. (Canceled)